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10/563,199	09/01/2006	John Brownlie	ERP02.001APC1	6472

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/563,199	BROWNLIE ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 8-19* is/are pending in the application.

4a) Of the above claim(s) *16-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 8-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/10/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 9, 2010 has been entered.

Amendment Entry

2. The amendment filed August 9, 2010 has been entered. Claims 1 and 8-19 are pending. Claims 1 and 18-19 has been amended. Claim 16-19 is withdrawn. Claims 1 and 8-15 are under examination.

Rejections Withdrawn

3. In view of Applicant's amendment and remark following objections/rejections are withdrawn.

a) The rejection of claims 1, 8, and 59 under 35 U.S.C. 103(a) as being unpatentable over Mackenzie et al EP 0415794A1 and Hymas et al US Application No. 20020150593 US Publication Date October 17, 2002 is withdrawn in light of applicant's amendment thereto and also the limitations of inactivated/attenuated or structural protein of *Streptococcus equi sub species zooepidemicus (S. zooepidemicus) and* inactivated/attenuated or structural protein *Chlamydophila* not disclosed by the art.

b) The rejection of claims 1, 8-9, 11, 40-41, and 59 under 35 U.S.C. 103(a) as being unpatentable over Mackenzie et al EP 0415794A1, Hymas et al US Application No. 20020150593 US Publication Date October 17, 2002 and Brown et al US Patent No. 5,661,006 Date August 26, 1997 is withdrawn in light of applicant's amendment thereto and also the limitations of inactivated/attenuated or structural protein of *Streptococcus equi sub species zooepidemicus (S. zooepidemicus) and* inactivated/attenuated or structural protein *Chlamydophila* not disclosed by the art.

c) The rejection of claims 1, 8-10, 12-14, 40-41, and 59 under 35 U.S.C. 103(a) as being unpatentable over Mackenzie et al EP 0415794A1, Hymas et al US Application No.

20020150593 US Publication Date October 17, 2002, and Acree et al US Patent No. 4,824,785 Date January 28, 1986 is withdrawn in light of applicant's amendment thereto and also the limitations of inactivated/attenuated or structural protein of *Streptococcus equi sub species zooepidemicus (S. zooepidemicus) and* inactivated/attenuated or structural protein *Chlamydophila* not disclosed by the art.

d) The rejection of claims 1, 8-9, 15, 57, and 59 under 35 U.S.C. 103(a) as being unpatentable over Mackenzie et al EP 0415794A1, Hymas et al US Application No. 20020150593 US Publication Date October 17, 2002, and Jacobs et al US Patent No. 6,682,745 Date January 27, 2004 US Filing Date January 27, 2000 is withdrawn in light of applicant's amendment thereto and also the limitations of inactivated/attenuated or structural protein *Chlamydophila* not disclosed by the art.

e) The rejection of claims 1, 8-10, 12-15, 40-42, 57, and 59 under 35 U.S.C. 103(a) as being unpatentable over Mackenzie et al EP 0415794A1, Hymas et al US Application No. 20020150593 US Publication Date October 17, 2002, Acree et al US Patent No. 4,824,785 Date January 28, 1986 and Jacobs et al US Patent No. 6,682,745 Date January 27, 2004 US Filing Date January 27, 2000 is withdrawn in light of applicant's amendment thereto and also the limitations of inactivated/attenuated or structural protein *Chlamydophila* not disclosed by the art.

f) The rejection of claims 1, 8-9, 11, 15, 40-42, 57, and 59 under 35 U.S.C. 103(a) as being unpatentable over Mackenzie et al EP 0415794A1, Hymas et al US Application No. 20020150593 US Publication Date October 17, 2002, Brown et al US Patent No. 5,661,006 Date August 26, 1997 and Jacobs et al US Patent No. 6,682,745 Date January 27, 2004 US Filing Date January 27, 2000 is withdrawn in light of applicant's amendment thereto and also the limitations of inactivated/attenuated or structural protein *Chlamydophila* not disclosed by the art.

g) Objection to claims 58 and 60-63 as being dependent upon a rejected base claim is withdrawn in light of applicants' cancellation of claims.

Information Disclosure Statement

4. The information disclosure statement filed 2/10/2010 has been considered. An initialed copy is enclosed.

New Grounds of Rejections

Claim Rejections- 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 and 8-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to an immunogenic composition comprising an agent capable of raising an immune response against *Mycoplasma cynos (M. cynos)* in a dog, wherein said agent comprises inactivated or attenuated *M. cynos,* or a structural protein of *M. cynos* or a nucleic acid encoding said structural protein, and further comprising an agent selected from the group consisting of: an agent capable of raising an immune response against *Streptococcus equi sub species zooepidemicus (S. zooepidemicus)* in a dog, wherein the agent capable of raising an immune response against *S. zooepidemicus* in a dog comprises inactivated or attenuated *S. zooepidemicus,* or a structural protein of *S. zooepidemicus* or a nucleic acid encoding said structural protein, and an agent capable of raising an immune response against a *Chlamydophila* in a dog, wherein the agent capable of raising an immune response in a dog against a *Chlamydophila* comprises inactivated or attenuated *Chlamydophila abortus, Chlamydophila psittaci, Chlamydophila felis, Chlamydophila muridarum, Chlamydophila pecorum, Chlamydophila pneumoniae, Chlamydophila suis, Chlamydophila trachomatis,* or a nucleic acid encoding said structural protein (claim 1); a pharmaceutical composition an immunogenic composition and a pharmaceutically acceptable carrier, diluent, or adjuvant (claim 8), further comprising any one or more of: an agent capable of raising an immune response in a dog against canine respiratory coronavirus (CRCV); an agent capable of raising an immune response in a dog

against canine parainfluenzavirus (CPIV); an agent capable of raising an immune response in a dog against canine adenovirus type 2 (CAV-2); an agent capable of raising an immune response in a dog against canine herpesvirus (CHV); and an agent capable of raising an immune response in a dog against *Bordetella bronchiseptica (B. bronchiseptica)* (claim 9), wherein the agent capable of raising an immune response in a dog against CRCV comprises inactivated or attenuated CRCV (claim 10), wherein the agent capable of raising an immune response in a dog against CRCV comprises a Spike protein or a hemagglutinin-esterase (HE) protein of CRCV, or an immunogenic portion of the Spike or HE protein (claim 11), wherein the agent capable of raising an immune response in a dog against CPIV comprises inactivated or attenuated CPIV (claim 12), wherein the agent capable of raising an immune response in a dog against CAV-2 comprises inactivated or attenuated CAV-2 (claim 13), wherein the agent capable of raising an immune response in a dog against CHV comprises inactivated or attenuated CHV (claim 14), wherein the agent capable of raising an immune response in a dog against *B. bronchiseptica* comprises inactivated or attenuated *B. bronchiseptica* (claim 15).

Moreover, the instant claims encompass a vast genus of agents encompassing inactivated or attenuated *M. cynos,* or a structural protein of *M. cynos* or a nucleic acid encoding said structural protein in an immunogenic composition that has the capability of raising a directed (unnamed) immune response against the bacteria of *M. cynos* in a dog, and further comprising an agent in said immunogenic composition that has the capability of raising a directed (unnamed) immune response against the bacteria selected from the group consisting of an inactivated or attenuated *S. zooepidemicus or Chlamydophila species aforementioned above,* or a structural protein of *S. zooepidemicus or Chlamydophila species aforementioned above,* or a nucleic acid encoding said structural protein of *S. zooepidemicus or Chlamydophila species aforementioned above in a dog* in the claimed composition.

Therefore to adequately describe the claimed genus of vast agents aforementioned above in a immunogenic composition, applicants must adequately describe the immunoepitopes that conveys the ability of induction of a directed (unnamed) immune response against the bacteria of *M. cynos* in a dog which further has the capability of raising a directed immune response against the bacteria selected from the group consisting of *S. zooepidemicus or Chlamydophila species aforementioned above* in a dog in the claimed composition.

The specification discloses a variety of different agents encompassing inactivated, attenuated, immunogenic fragments, derivatives, nucleic acids encoding amino acids, derivatives, etc. for the recited functions (see pgs 1-30). The specification discloses a study comprised animals from a kennel (600 dogs) with a history of endemic Canine Infection Respiratory Disease, wherein all dogs at the kennel were vaccinated with KAVAK DA2 PIP69 (Fort Dodge), which is a live attenuated vaccine for distemper virus, CAV-2, CPIV and canine parvovirus and KAVAK L against Leptospirosis (see pg. 56-57). The specification discloses each week 2-3 dogs were selected arbitrarily for sampling of the dogs bronchial alveolar lavage (BAL) after vaccinated above over a 2 year period from 1999 to 2001 (see pg. 57-58). The specification discloses after sampling BAL from dogs, the dogs were also graded for the severity of clinical respiratory score into the following categories: (1) No respiratory signs (2) Mild cough etc. in a survey (see pg. 57-65). Moreover, said data indicated does not provide a correlation between the structure of the immunoepitopes and any type of directed unnamed immune response recited in the immunogenic composition set forth in the instant claims.

Therefore the specification is limited providing a survey disclosing the association of *Streptococcus equi sub species zooepidemicus* with canine infectious respiratory disease, the association of *Mycoplasmas cynos* with canine infectious respiratory disease (see pgs 42-54). The specification does not provide guidance by administering **agents** (antigenic determinants) resulting in the recited induced functions in the claimed compositions as discussed.

Furthermore the specification does not provide guidance on any agents that are directed to a specific immune response against the microorganism itself of any type of bacteria aforementioned above. Moreover Applicant has not demonstrated how any immunoepitopes of *M. cynos, S. zooepidemicus* in a dog, or any species of *Chlamydophila* correlative to the recited function of induced functions recited in the claimed compositions. Moreover, the claims are silent with regard to what agents are capable of its induced functions recited in the composition as claimed. Furthermore Applicants have not disclosed any **agents** that are representative of the above genus capable of its induced functions recited in the composition. Thus, applicant was not in possession of the claimed genus.

Moreover, the specification, does not disclose distinguishing and identifying features of a representative number of members of the genus of (antigenic determinants) to which the claims

are drawn, such as a correlation between the structure for the genus of (antigenic determinants) and its recited function aforementioned above. Therefore, the specification fails to adequately describe at least a substantial number of members of the genus of aforementioned above.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description'' Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

The *Guidelines* further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of (antigenic determinants) aforementioned above, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of (antigenic determinants) with the recited activities. Therefore, because the art is unpredictable, in accordance with the *Guidelines*, the description of antigenic determinants is not deemed representative of the immunoepitopes of the genus of agents and the

induced functions recited in the methods to which the claims refer and therefore the claimed invention is not properly disclosed.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 8-9, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over (Mackenzie et al EP 0415794A1 Date September 6, 1991), (Hansen et al US Patent No. 5,665,363 Date September 9, 1997), and (Hymas et al US Application No. 20020150593 US Publication Date October 17, 2002).

Mackenzie et al teach an immunogenic composition comprising whole cells from *M. cynos* (see claims 1-2 and pg. 2 lines 40-50 pg. 3 lines 51-55) further and a pharmaceutically acceptable carrier or adjuvant administered to animals such as a dog (see abstract, pg. 2 lines 34-54, pg. 3 lines 15-17, pg. 4 last paragraph). Mackenzie et al teach an immunogenic composition comprising *Chlamydia psittaci which is also defined as Chlamydophila psittaci* as evidenced by Saunders Comprehensive Veterinary Dictionary, 3 ed. 2007 (see attachment of definition) (see claims 1-2 and pg. 2 lines 40-50 pg. 3 lines 51-55, pg. 4 lines 1-20, and pg. 10 "Vaccines) administered to animals such as a dog.

Mackenzie et al does not teach an immunogenic composition, wherein the agent comprises inactivated or attenuated *M. cynos*, or a structural protein of *M. cynos* or a nucleic acid encoding said structural protein, and further comprising an agent selected from the group

consisting of: an agent capable of raising an immune response against *Streptococcus equi sub species zooepidemicus (S. zooepidemicus)* or *Chlamydophila* species aforementioned above in a dog, wherein the agent capable of raising an immune response against *S. zooepidemicus* or *Chlamydophila* species aforementioned above in a dog comprises inactivated or attenuated *S. zooepidemicus* or *Chlamydophila* species aforementioned above, or a structural protein of *S. zooepidemicus* or *Chlamydophila* species aforementioned above in a nucleic acid encoding said structural protein. Furthermore, Mackenzie et al does not teach an immunogenic composition, further comprising any one or more of: an agent capable of raising an immune response in a dog against (CRCV); an agent capable of raising an immune response in a dog against (CPIV); an agent capable of raising an immune response in a dog against (CAV-2); an agent capable of raising an immune response in a dog against (CHV); an agent capable of raising an immune response in a dog against *B. bronchiseptica.* Furthermore, Mackenzie et al does not teach an immunogenic composition, wherein the agent capable of raising an immune response in a dog against CPIV comprises inactivated or attenuated CPIV, wherein the agent capable of raising an immune response in a dog against *B. bronchiseptica* comprises inactivated or attenuated *B. bronchiseptica*.

Hansen et al teach a biologically active pellet containing a biologically active material and administering subcutaneously into animal such as dogs biologically active pellets in an effective immune stimulating amount (see abstract and column 10 lines 1-10). Hansen et al teach a biologically active material is any material which stimulates an immune response in the animal and will cause the formation of antibodies or induce other resistance mechanisms by the animal (see column 3 lines 30-40). Hansen et al teach viruses (live or killed), attenuated viruses, bacteria (live or killed), detoxified toxins are all well known biologically active materials and particularly useful ingredients in vaccines, bacterins (i.e. bacterin-toxoids are a suspension of killed bacteria along with toxoids) used to protect animals against specific diseases (see column 3 lines 30-67). Hansen et al teach biologically active materials are *Mycoplasma sp. Bordetella bronchiseptica*, canine parvovirus, canine adenovirus, canine distemper, canine parainfluenza, and Chlamydia psittaci (see column lines 60-67, column 4 lines 1-20). Therefore the biological active materials of Hansen et al correlate to: a) an agent capable of raising an immune response against a *Chlamydophila* comprising an inactivated *Chlamydophila psittaci* in a dog; b) an agent capable

of raising an immune response in a dog against an inactivated CPIV, an agent capable of raising an immune response in a dog against an inactivated *B. bronchiseptica*. Hansen et al teach pharmaceutical pellets prepared with a liquid suspension containing bacterial cells (i.e. bacterial culture fluids) (see column 4 lines 50-60 and Example 2) in a composition comprising an immunogenic composition and adsorbed on aluminum hydroxide gel thus in a pharmaceutically acceptable carrier (see example 2 and column 4 lines 1-25).

Hymas et al teach an immunogenic composition comprising whole cell, inactivated bacterin from *Mycoplasma species* (see 0012) (see 0028, column 5, 0045, 0011). Hymas et al teach combination of vaccines used to provide immunity against viral or bacterial infections comprising attenuated organisms or inactivated whole organisms in order to present antigens to the recipient's immune system sufficient to produce a protective immune response without giving the recipient the disease (see 0008).

It would have been prima facie obvious at the time the invention was made to inactivate the whole cell Mycoplasma compositions of Mackenzie et al. in the manner taught by Hymas et al in order to take advantage of the increased safety associated with the use of an inactivated pathogen.

It would have been equally obvious at the time the invention was made to inactivate the composition *Chlamydophila psittaci* of Mackenzie et al in the manner taught by Hansen et al in order to take advantage of delivering biologically active materials in a manner that eliminates lean tissue damage to the animal following vaccination without other undesirable effects.

Furthermore given that cited antigens and combination immunogenic compositions are well known in the art leading to predictable results, it would be obvious to use cited antigens in an immunogenic composition disclosed in Mackenzie et al and Hansen et al to create a combination vaccine with cited antigens, thus, it remains obvious to combine them (cited antigens and combination immunogenic compositions), even without an express statement of motivation. KSR forcloses the argument that a specific teaching, suggestion, or motivation is required to support a finding an obviousness. See the recent Board Decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007 (citing KSR, 82 USPQ2d at 1396) available at (http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

8. Claims 1, 8-10, and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over (Mackenzie et al EP 0415794A1 Date September 6, 1991), (Hansen et al US Patent No. 5,665,363 Date September 9, 1997), (Hymas et al US Application No. 20020150593 US Publication Date October 17, 2002), and (Acree et al US Patent No. 4,824,785 Date January 28, 1986).

Mackenzie et al teach an immunogenic composition comprising whole cells from *M. cynos* (see claims 1-2 and pg. 2 lines 40-50 pg. 3 lines 51-55) further and a pharmaceutically acceptable carrier or adjuvant administered to animals such as a dog (see abstract, pg. 2 lines 34-54, pg. 3 lines 15-17, pg. 4 last paragraph). Mackenzie et al teach an immunogenic composition comprising *Chlamydia psittaci which is also defined as Chlamydophila psittaci* as evidenced by Saunders Comprehensive Veterinary Dictionary, 3 ed. 2007 (see attachment of definition) (see claims 1-2 and pg. 2 lines 40-50 pg. 3 lines 51-55, pg. 4 lines 1-20, and pg. 10 "Vaccines) administered to animals such as a dog.

Mackenzie et al does not teach an immunogenic composition, wherein the agent comprises inactivated or attenuated *M. cynos*, or a structural protein of *M. cynos* or a nucleic acid encoding said structural protein, and further comprising an agent selected from the group consisting of: an agent capable of raising an immune response against *Streptococcus equi sub species zooepidemicus (S. zooepidemicus)* or *Chlamydophila* species aforementioned above in a dog, wherein the agent capable of raising an immune response against *S. zooepidemicus* or *Chlamydophila* species aforementioned above in a dog comprises inactivated or attenuated *S. zooepidemicus* or *Chlamydophila* species aforementioned above, or a structural protein of *S. zooepidemicus* or *Chlamydophila* species aforementioned above in a nucleic acid encoding said structural protein. Furthermore, Mackenzie et al does not teach an immunogenic composition, further comprising any one or more of: an agent capable of raising an immune response in a dog against (CRCV); an agent capable of raising an immune response in a dog against (CPIV); an agent capable of raising an immune response in a dog against (CAV-2); an agent capable of raising an immune response in a dog against (CHV); an agent capable of raising an immune response in a dog against *B. bronchiseptica.* Furthermore, Mackenzie et al does not teach an immunogenic composition, wherein the agent capable of raising an immune response in a dog against CPIV comprises inactivated or attenuated CPIV, wherein the agent capable of raising an

immune response in a dog against *B. bronchiseptica* comprises inactivated or attenuated *B. bronchiseptica*.

Hansen et al teach a biologically active pellet containing a biologically active material and administering subcutaneously into animal such as dogs biologically active pellets in an effective immune stimulating amount (see abstract and column 10 lines 1-10). Hansen et al teach a biologically active material is any material which stimulates an immune response in the animal and will cause the formation of antibodies or induce other resistance mechanisms by the animal (see column 3 lines 30-40). Hansen et al teach viruses (live or killed), attenuated viruses, bacteria (live or killed), detoxified toxins are all well known biologically active materials and particularly useful ingredients in vaccines, bacterins (i.e. bacterin-toxoids are a suspension of killed bacteria along with toxoids) used to protect animals against specific diseases (see column 3 lines 30-67). Hansen et al teach biologically active materials are *Mycoplasma sp. Bordetella bronchiseptica*, canine parvovirus, canine adenovirus, canine distemper, canine parainfluenza, and Chlamydia psittaci (see column lines 60-67, column 4 lines 1-20). Therefore the biological active materials of Hansen et al correlate to: a) an agent capable of raising an immune response against a *Chlamydophila* comprising an inactivated *Chlamydophila psittaci* in a dog; b) an agent capable of raising an immune response in a dog against an inactivated CPIV, an agent capable of raising an immune response in a dog against an inactivated *B. bronchiseptica*. Hansen et al teach pharmaceutical pellets prepared with a liquid suspension containing bacterial cells (i.e. bacterial culture fluids) (see column 4 lines 50-60 and Example 2) in a composition comprising an immunogenic composition and adsorbed on aluminum hydroxide gel thus in a pharmaceutically acceptable carrier (see example 2 and column 4 lines 1-25).

Hymas et al teach an immunogenic composition comprising whole cell, inactivated bacterin from *Mycoplasma specie* (see 0012) (see 0028, column 5, 0045, 0011). Hymas et al teach combination of vaccines used to provide immunity against viral or bacterial infections comprising attenuated organisms or inactivated whole organisms in order to present antigens to the recipient's immune system sufficient to produce a protective immune response without giving the recipient the disease (see 0008).

Acree et al teach respiratory symptom of canine coronavirus disease is a slight nasal discharge (see column 2 lines 15-25) and further teach canine coronavirus found in the trachea of

dogs after administering canine coronavirus intranasally (see example 2) which necessarily teach canine respiratory coronavirus (CRCV) as evidence to the contrary. Acree et al teach an immunogenic composition comprising an attenuated modified live canine coronavirus (see column 3 lines 20-67) to produce an immunological response in dogs (see column 5 lines 20-30). Acree et al teach any combination or singularly of additional attenuated modified live viruses or killed viruses such as Canine Parainfluenza virus, Canine Adenovirus II, and Canine Herpesvirus (see column 4 lines 1-15).

It would have been prima facie obvious at the time the invention was made to inactivate the whole cell Mycoplasma compositions of Mackenzie et al. in the manner taught by Hymas et al in order to take advantage of the increased safety associated with the use of an inactivated pathogen.

It would have been equally obvious at the time the invention was made to inactivate the composition *Chlamydophila psittaci* of Mackenzie et al in the manner taught by Hansen et al in order to take advantage of delivering biologically active materials in a manner that eliminates lean tissue damage to the animal following vaccination without other undesirable effects.

Furthermore given that cited antigens and combination immunogenic compositions are well known in the art leading to predictable results, it would be obvious to use cited antigens in an immunogenic composition disclosed in Mackenzie et al, Hansen et al, and Acree et al to create a combination vaccine with cited antigens, thus, it remains obvious to combine them (cited antigens and combination immunogenic compositions), even without an express statement of motivation. KSR forcloses the argument that a specific teaching, suggestion, or motivation is required to support a finding an obviousness. See the recent Board Decision Ex parte Smith, -- USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007 (citing KSR, 82 USPQ2d at 1396) available at (http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

9. Claims 1, 8-9, 11-12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over (Mackenzie et al EP 0415794A1 Date September 6, 1991), (Hansen et al US Patent No. 5,665,363 Date September 9, 1997), (Hymas et al US Application No. 20020150593 US Publication Date October 17, 2002), and (Brown et al US Patent No. 5,661,006 Date August 26, 1997).

Mackenzie et al teach an immunogenic composition comprising whole cells from *M. cynos* (see claims 1-2 and pg. 2 lines 40-50 pg. 3 lines 51-55) further and a pharmaceutically acceptable carrier or adjuvant administered to animals such as a dog (see abstract, pg. 2 lines 34-54, pg. 3 lines 15-17, pg. 4 last paragraph). Mackenzie et al teach an immunogenic composition comprising *Chlamydia psittaci which is also defined as Chlamydophila psittaci* as evidenced by Saunders Comprehensive Veterinary Dictionary, 3 ed. 2007 (see attachment of definition) (see claims 1-2 and pg. 2 lines 40-50 pg. 3 lines 51-55, pg. 4 lines 1-20, and pg. 10 "Vaccines) administered to animals such as a dog.

Mackenzie et al does not teach an immunogenic composition, wherein the agent comprises inactivated or attenuated *M. cynos*, or a structural protein of *M. cynos* or a nucleic acid encoding said structural protein, and further comprising an agent selected from the group consisting of: an agent capable of raising an immune response against *Streptococcus equi sub species zooepidemicus (S. zooepidemicus)* or *Chlamydophila* species aforementioned above in a dog, wherein the agent capable of raising an immune response against *S. zooepidemicus* or *Chlamydophila* species aforementioned above in a dog comprises inactivated or attenuated *S. zooepidemicus* or *Chlamydophila* species aforementioned above, or a structural protein of *S. zooepidemicus* or *Chlamydophila* species aforementioned above in a nucleic acid encoding said structural protein. Furthermore, Mackenzie et al does not teach an immunogenic composition, further comprising any one or more of: an agent capable of raising an immune response in a dog against (CRCV); an agent capable of raising an immune response in a dog against (CPIV); an agent capable of raising an immune response in a dog against (CAV-2); an agent capable of raising an immune response in a dog against (CHV); an agent capable of raising an immune response in a dog against *B. bronchiseptica.* Furthermore, Mackenzie et al does not teach an immunogenic composition, wherein the agent capable of raising an immune response in a dog against CPIV comprises inactivated or attenuated CPIV, wherein the agent capable of raising an immune response in a dog against *B. bronchiseptica* comprises inactivated or attenuated *B. bronchiseptica*.

Hansen et al teach a biologically active pellet containing a biologically active material and administering subcutaneously into animal such as dogs biologically active pellets in an effective immune stimulating amount (see abstract and column 10 lines 1-10). Hansen et al teach

a biologically active material is any material which stimulates an immune response in the animal and will cause the formation of antibodies or induce other resistance mechanisms by the animal (see column 3 lines 30-40). Hansen et al teach viruses (live or killed), attenuated viruses, bacteria (live or killed), detoxified toxins are all well known biologically active materials and particularly useful ingredients in vaccines, bacterins (i.e. bacterin-toxoids are a suspension of killed bacteria along with toxoids) used to protect animals against specific diseases (see column 3 lines 30-67). Hansen et al teach biologically active materials are *Mycoplasma sp. Bordetella bronchiseptica*, canine parvovirus, canine adenovirus, canine distemper, canine parainfluenza, and Chlamydia psittaci (see column lines 60-67, column 4 lines 1-20). Therefore the biological active materials of Hansen et al correlate to: a) an agent capable of raising an immune response against a *Chlamydophila* comprising an inactivated *Chlamydophila psittaci* in a dog; b) an agent capable of raising an immune response in a dog against an inactivated CPIV, an agent capable of raising an immune response in a dog against an inactivated *B. bronchiseptica*. Hansen et al teach pharmaceutical pellets prepared with a liquid suspension containing bacterial cells (i.e. bacterial culture fluids) (see column 4 lines 50-60 and Example 2) in a composition comprising an immunogenic composition and adsorbed on aluminum hydroxide gel thus in a pharmaceutically acceptable carrier (see example 2 and column 4 lines 1-25).

Hymas et al teach an immunogenic composition comprising whole cell, inactivated bacterin from *Mycoplasma specie* (see 0012) (see 0028, column 5, 0045, 0011). Hymas et al teach combination of vaccines used to provide immunity against viral or bacterial infections comprising attenuated organisms or inactivated whole organisms in order to present antigens to the recipient's immune system sufficient to produce a protective immune response without giving the recipient the disease (see 0008).

It would have been prima facie obvious at the time the invention was made to inactivate the whole cell Mycoplasma compositions of Mackenzie et al. in the manner taught by Hymas et al in order to take advantage of the increased safety associated with the use of an inactivated pathogen.

It would have been equally obvious at the time the invention was made to inactivate the composition *Chlamydophila psittaci* of Mackenzie et al in the manner taught by Hansen et al in

order to take advantage of delivering biologically active materials in a manner that eliminates lean tissue damage to the animal following vaccination without other undesirable effects.

Brown et al teach a canine coronavirus which causes respiratory diseases in dogs and respiratory symptoms of the canine coronavirus include nasal and ocular discharge (see column 1) which necessarily teaches canine respiratory coronavirus (CRCV) as evidence to the contrary. Brown et al teach an immunogenic composition comprising a canine coronavirus spike protein administered to dogs against canine coronavirus infection (see abstract, column 6, column 7 lines1-35).

Furthermore given that cited antigens and combination vaccines are well known in the art leading to predictable results, it would be obvious to use cited antigens in an immunogenic composition disclosed in Mackenzie et al, Hansen et al, and Brown et al to create a combination vaccine with cited antigens, thus, it remains obvious to combine them (cited antigens and combination immunogenic compositions), even without an express statement of motivation. KSR forcloses the argument that a specific teaching, suggestion, or motivation is required to support a finding an obviousness. See the recent Board Decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007 (citing KSR, 82 USPQ2d at 1396) available at (http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

Conclusion

10. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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